DECLARATION UNDER 37 C.F.R. § 1.132 OF THIERRY MARNAY		
	Application #	10/018,402
	Confirmation #	1151
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	First Inventor	MARNAY
	Art Unit	3738
	Examiner	Miller, Cheryl L.
	Docket #	P06794US00/MP

I, Thierry Marnay, declare that:

1. I am one of the inventors of the above identified application.

2. I have extensive experience in the field of degenerative disease and spine arthroplasty, both as a surgeon who has performed hundreds of operations, and as an inventor of improvements in spine arthoplasty. A number of my prior inventions in spine arthoplasty are the subject of nine issued United States Patents, as listed in the attached Appendix. In addition, I have written and lectured extensively in the field of spine arthoplasty. A more complete statement of my background in the field of spine arthoplasty is set forth in the attached appendix to this declaration.

3. I am the named inventor of U.S. Patent No. 5,314,477 (hereinafter "the '477 patent") cited in the Office Action mailed March 1, 2004 in the above identified application.

4. In one form of the present invention, an intervertebral implant comprises an upper part and a lower part, each part having a single keel which serves as an anchor to secure the implant to adjacent upper and lower vertebrae.

5. The '477 patent discloses an implant in which a pair of anchors are used to secure each of the upper and lower parts of the implant into each adjacent vertebrae.

6. At the time of the '477 patent and prior to the present invention, it was considered necessary to include a pair of anchors on each of the upper and lower parts of an intervertebral implant. A pair of anchors on each part was considered essential in providing the necessary stability of the implant relative to the respective vertebraes between which the implant was inserted. Having a pair of anchors provides enhanced stability as compared with a single anchor in that two anchors stabilize the implant relative to the adjacent vertebrae. For example, analogizing to a catamaran, the effect of having two keels in contact with the surface of the water enhances the stability and balance of the craft relative to the surface of the water. Were the vessel to consist of a single keel in contact with the water, the vessel would be substantially less stable. Balancing or pivoting on a single keel would be subject to the effects of inertia and the forces of gravity on the craft. Similarly, having two anchors in contact with each adjacent vertebrae enhances the stability of the implant and provides the necessary stable connection between the vertebrae and the implant.

7. An additional factor why a pair of anchors on each part of the implant was considered essential was that should the vertebrae have a surface facing the intervertebral space which is not of sufficient integrity for insertion of the anchor, e.g., the vertebrae bone is deteriorated or the surface is uneven, having two anchors enhances the likelihood that the implant will be securely attached to the damaged vertebrae bone. In such a manner, even if one of the anchors is not firmly secured to the vertebrae due to the deterioration of the bone, at least the second anchor will be firmly secured into the vertebrae, thereby firmly securing the prior two anchor implant to a damaged vertebrae bone.

8. There then came a time when it was deemed desirable to develop a less invasive implant. However, at the time, it was not apparent how one could redesign the implant to be less invasive, including reducing its size and mass, while providing for the necessary stability which was thought to require a pair of anchors.

9. The conception and subsequent development of a redesigned, less invasive implant represents a major change in implant design. In fact, the development of the present single keel implant, starting from the design shown in my '477 patent took over five years. During this period, the implant was completely redesigned in an effort to reduce its size and mass, while maintaining the required stability of the implant shown in the '477 patent. In addition, new and different insertion tools were required and are presently the subject of other patent applications.

10. A surprising key discovery of the redesigned implant was that a single keel can provide the necessary stability and secure anchoring of the implant to the vertebrae to an extent once believed achievable only by using a pair of anchors. Therefore, a single keel implant represents a major unexpectedly advantageous deviation from the prior art pair of anchors.

11. A single keel, as compared with a pair of anchors, provides enhanced features and advantages not provided or contemplated by prior implants having a pair of anchors. The present single keel implant is less invasive to insert because it allows a reduction in the overall size of the implant and allows for a reduction in the size of the instrumentation required for inserting the implant.

12. A further benefit of a single keel as compared with a pair of anchors is that the present single keel makes it easier to center the implant. The single keel provides a

guide for the middle of the vertebral body which the two anchor implant does not provide. With the present single keel concept, centering on the vertebrae which is checked with fluoroscopy followed by cutting with a chisel, insures centering of the slots.

13. Another significant benefit of a single keel implant concerns the problem of having to navigate in an around major blood vessels located just in front of the spine, namely the arterial and venous branches, as shown in the picture below. A particularly sensitive and difficult facet of anterior disc replacement, i.e., entering of the disc space from the patient's anterior, is navigating the instrumentation between these vessels without injuring them. Thus, another significant advantage of the single keel implant is that it requires a smaller lateral space and thus a smaller vascular separation of the blood vessels, in contrast with the two anchor implant which requires a larger separation of these vessels and hence more physical exertion upon these vessels. To illustrate, in the L5-S1 disc space, the obliquity of the left iliac vein places this vessel in very close proximity to the disc space at the upper left portion of the space. As a result thereof, increased dissection and traction on this vein was required for a two anchor plate in order to create a space for a double chisel for cutting two keels in the L5 vertebral body. There is an analogous situation when preparing cuts in the in L4-L5 disc space wherein providing a cut for the lower right keel needed extensive retraction of the left iliac vein.

14. A further advantage of the present single keel implant is that it allows for chiseling both an upper keel slot and a lower keel slot in the adjacent vertebrae simultaneously. As a result, the upper and lower keel slots will be in alignment with one another providing for proper alignment of the inserted implant. This should be contrasted with the prior two anchor implant which did not allow room within the intervertebral space for an instrument simultaneously to chisel all four cuts, i.e., two above and two below. As a result, prior two anchors slots were first chiseled above and then below or vice versa and thus there was no guarantee that the upper slots and lower slots would be properly aligned with one another.

15. Yet another advantage of the present single keel implant is that it reduces the chances of fracturing the vertebral body such as could occur in the case of adjacent two level disc replacement. Unlike a two anchor implant which requires two cuts in each vertebral body, the present single keel implant minimizes the number of cuts. As a result, the present single keel limits the risk of fregilize of the vertebral body, especially in the case of osteoporosis, and limits the possible risk of vertebral body failure.

16. A further advantage of the present single keel implant is that it provides greater flexibility in the geometry of the implant surface, i.e., plates, abutting the respective upper and lower vertebrae, thus allowing greater adaptation of the base plates to meet the contours of the anatomy corresponding to the adjacent vertebral body.

17. In summary it would not have been obvious to switch from an implant having a pair of anchors to an implant having a single keel in that prior to the present invention, it was believed essential to have a pair of anchors. The prior art, especially my prior '477 patent fails to provide any motivation for one of ordinary skill in the art to modify it to form a single keel implant. Moreover, the prior art fails to teach or suggest how one would modify a pair of anchors system to a single keel system while maintaining the necessary stability which, prior to the invention, was thought to require a pair of anchors. In light of the presumed essential benefits of a pair of anchors, there was no contemplation in the art, let alone in the prior art of the '477 patent or any of the other prior art references cited by the Examiner, to suggest a single keel implant.

18. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 USC § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

June 18th 2004
Date

Thierry Marnay

Biography of Dr. Thierry Marnay

Dr. Marnay was born is Paris and graduated from medical school in Paris before moving to Montpellier in the south of France for surgical training. He completed his orthopedic experience in the field of spine surgery under the direction of famous doctors including Roy Camille, R. Louis and J. Senegas. Dr. Marnay spent six years as a surgeon at Montpellier University Hospital before creating the spine department in Clinique du Parc. His research interest during his residency and training was dedicated to total joint replacement and scoliosis treatment. Dr. Marnay published the first paper relating to spinal balance and spondylolisthesis in 1983 in the French Orthopedic and Traumatology Journal (RCO). Dr. Marnay created the first titanium device for scoliosis and segmental fixation of the spine in 1989 and participated in research related to anterior spine fixation.

Dr. Marnay's work through the 1980's concerned disc replacement. He started the first series of spine replacements with 64 patients in the 1990's with "Prodisc-I" which is the subject matter of U.S. Patent No. 5,314,477. As the pioneer of miniinvasive technology with thoracoscopy and lumbar miniinvasive access, he trained a number of surgeons in this new technology. He combined miniinvasive lumbar technology and total disc replacement to start another study. In 1999 he created a training center dedicated to disc replacement techniques in Montpellier.

Dr. Marnay is a founding member of the Spine Arthroplasty Society and was the chairman of the second global meeting on spine arthroplasty in Montpellier in 2002. Dr. Marnay presented a seven to eleven year follow up relating to the Prodisc-I replacement and the preliminary results of his work is spinal balance and total disc replacement. Dr. Marnay works closely with American and world wide centers which are now performing his technique including the Prodisc II which is the subject matter of the present application. Dr. Marnay presented his long term experience relating to disc replacement at the NASS congress in Montreal. He is the "father" of the two most important topics debated today in the spine field, namely spinal balance and total disc replacement.

Dr. Marnay is associated with Montpellier and Marseille Universities for purposes of research and teaching. Dr. Marnay has been issued the following U.S. Patents:

6,206,879	Osteosynthetic holding system.
6,086,588	Osteosynthesis system for vertebra arthrodesis
6,077,263	Vertebral osteosynthetic system.
5,723,013	Space implant for substituting missing vertebrae.
5,713,899	Cervical cage designed for the performance of intersomatic arthrodesis.
5,658,285	Rehabitable connecting-screw device for a bone joint, intended in particular for stabilizing at least two vertebrae.
5,527,315	Spinal osteosynthesis rod with three branches.
5,314,477	Prosthesis for intervertebral discs and instruments for implanting it.

5,261,913 Device for straightening, securing, compressing and elongating the spinal column.

Descriptively, Dr. Marnay's inventions and patents include the following:

1. ALS plate: plates for posterior fixation in case of spondylolisthesis
2. Cotyle Carat: total hip replacement acetabulum with screwed acetabulum and with a polyethylene inserts.
3. Epiphysis locking nail: locking nail with external vizor for hip fractures and hip osteotomies.
4. Spine System: posterior universal system for spinal fixation in Titanium with self stable clamps (hooks linked together independent of the main rod system) and pedicular screws.
5. Prodisc-I: total disc replacement as shown in the '477 patent.
6. Cervical disc replacement: total cervical disc with two plates from fixation.
7. HMA screws: system of hollow screws with inside rehabitation of bone for interbody fusion.
8. MACS: anterior spine fixation with standard or HMA screws adapted to videoscopic and thoracoscopic surgery.
9. Spine System Evolution: posterior universal fixation for the spine.
10. Plate-cage titanium: cervical cages with two half plates for anterior cervical spine fusion.
11. Prodisc-II: total disc replacement using the subject matter of the present application. Four thousand cases have been performed world wide.
12. Prodisc C: total cervical disc replacement.